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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,267	03/06/2001	Rachel A. Meyers	10448-025001/MPI2000-061P	5520

7590

10/08/2002

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EXAMINER

EINSMANN, JULIET CAROLINE

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 10/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/801,267

Applicant(s)

MEYERS, RACHEL A.

Examiner

Juliet C Einsmann

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-36 is/are pending in the application.
- 4a) Of the above claim(s) 8-17 and 19-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-7 and 18 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 10 is acknowledged.
2. Applicant's amendment filed 7/2/02 (paper number 10) has been entered. Claim 1 was cancelled and claims 2-5, 7 and 18 were amended. Claims 2-7 and 18 are examined herein.

Information Disclosure Statement

3. The information disclosure statements filed 9/4/01 and 1/16/02 have been entered into the file and considered (paper numbers 6 and 7). References AF and AL were modified on the substitute-1449 so as to delete the reference to the internet sites and to include the page numbers of the references. Reference AM was lined through because it does not contain a complete citation. This reference has been considered, but if applicant wishes for the reference to appear on the face of any eventually issued patent a new 1449 with the complete citation should be submitted.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code (see pages 11 and 14). See MPEP § 608.01.
5. The specification is also objected to because it repeatedly refers to "ATCC as Accession Number ____." The presence of the blank throughout the specification leaves the specification unclear (see at least pages 2, 3, 11, 24, and 28-34). Amendment of the specification to recite the accession number is required. It is noted that, in the interest of compact prosecution, Applicants

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may refrain from amending the claims until the time of the actual deposit as set forth in 37 CFR 1.801-1.809. However, upon such a deposit, amendment of the specification is required.

Claim Objections

6. Claim 18 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 18 is of broader scope than claim 2 from which it depends, therefore it fails to properly limit the claim from which it depends.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 2-7 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the DNA insert of the plasmid deposited with ATCC is required to practice the claimed invention. As such, they must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise known and readily available to the public. If it is not so obtainable or available, the requirements of 35 USC 112, first paragraph may be satisfied by an enabling deposit of the plasmid.

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It is noted that Applicants have deposited the organism but there is not indication in the specification as to the public availability of the plasmid (see specification pages 11-12), thus it is considered insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met. If a deposit has been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released upon issuance of a patent would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that :

- (a) during pendency of the application, accession to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

Amendment of the specification to recite the date of the deposit and the proper name of the deposited plasmid (i.e. the ATCC accession number) is also required to satisfy the deposit requirement.

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9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 2-7 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite because of the recitation "the DNA insert of the plasmid deposited with ATCC as Accession Number _____" because the claims do not particularly point out the claimed subject matter. In the interest of compact prosecution, Applicants may refrain from amending the claims until the time of the actual deposit as set forth in 37 CFR 1.801-1.809. Failure to amend claim 2 will, however, result in abandonment for failure to prosecute.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lawson et al. (Biochemistry, 1993, Vol. 32, pages 8987-8993) in view of Ahern (The Scientist, Vol. 9, No. 15, p. 20, 1995).

Lawson et al. provide a compound which selectively hybridizes to a nucleic acid molecule comprising SEQ ID NO: 1 or SEQ ID NO: 3 or encoding SEQ ID NO: 2. Lawson et al. teach a cDNA encoding bovine pyruvate dehydrogenase phosphatase (fig. 2). This compound has 92.5% local similarity with instant SEQ ID NO: 3. An alignment is provided at the end of

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this office action. The sequence on the top row is instant SEQ ID NO: 1 and the sequence on the bottom row is the sequence provided by Lawson et al. This sequence would be expected to selectively hybridize to SEQ ID NO: 3 even under conditions of high stringency.

Lawson et al. does not include the compound in a kit with instructions for use.

However, the inclusion of reagents for the practice of molecular biology techniques in kits with instructions for use was routine in the art at the time the invention was made. For example, Ahern teaches that a lab can purchase kits that contain all of the biochemicals needed to perform research applications from the molecular level right up to the level of the organism (p. 4 of 5) (Reference provided from a web-site print out; page numbers refer to the web site print out). Further Ahern teaches that such kits supply all of the necessary reagents for a particular research application and provides them with specific instructions to follow (p. 4 of 5).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the reagents taught by Lawson et al. into a kit for the further practice of methodologies using the cDNA taught by Lawson et al. The ordinary practitioner would have been motivated to provide such a kit in order to provide other scientists with the means to utilize the cDNA taught by Lawson et al. in molecular biology research, since Ahern et al. teach "The large selection of prepared biochemicals and kits for specific applications has certainly made life easier for countless researchers (p. 5 of 5)."

Conclusion

13. Claims 1-7 are free of the prior art. The closest prior art is provided by Lawson et al. who provide a cDNA encoding bovine pyruvate dehydrogenase phosphatase (fig. 2). This compound has 92.5% local similarity with instant SEQ ID NO: 3. An alignment is provided at

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the end of this office action. The sequence on the top row is instant SEQ ID NO: 1 and the sequence on the bottom row is the sequence provided by Lawson et al. The prior art does not teach an isolated nucleic acid as recited in claim 1. Thus, claims 1-7 are free of the prior art.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

September 16, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600


Juliet C. Einsmann
Examiner
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Query Match 88.0%; Score 1417.4; DB 4; Length 1900;
Best Local Similarity 92.5%; Pred. No. 0;
Matches 1490; Conservative 0; Mismatches 121; Indels 0; Gaps 0;

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